Adverse Drug Reactions

Frequently Asked Questions

VA Center for Medication Safety
And VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

1. What is an adverse drug reaction as opposed to a side effect or allergy?

An *adverse drug reaction*, is "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function." An *allergy* is a type of adverse drug reaction.
The term *adverse drug reaction* has replaced *side effect*, which refers to an expected and known effect of a drug that is not the intended therapeutic outcome, in part because for new drugs there may be unknown side effects. Thus, any adverse unintended clinical outcome that occurs temporally with a drug should be considered as a possible adverse drug reaction.
In sum, an *adverse drug reaction* is **harm or injury caused by a medication**.

2. Why should we document possible adverse drug reactions

The purpose of documenting is to prevent future injuries.

3 . Who should document adverse drug reactions?

Any healthcare provider caring for a patient.

4. *When should an adverse drug reaction be documented?*

It is most important for providers to document and/or report ***any* suspected drug reaction** for a new drug (i.e., within 3 years of entry to market) and **suspected *severe* drug reactions** for any drug, no matter when the drug entered the market.

5. Where should adverse drug reactions be documented?

It is generally best to document the event in your clinic note and also enter the information in the allergy/adverse drug event field. This not only highlights the adverse reaction on the cover sheet but also can help trigger alerts for you or other providers. This can be done by you or a clinical pharmacist. Please consult local policy at your institution, as well, because reporting requirements may differ.

6. How are adverse drug reactions entered into the allergy/adverse drug event field?

This simple process takes about 30 seconds. Use the Order menu in CPRS, click on Allergies , enter the drug name and complete the form. For details see,
http://www.vapbm.org/vamedsafe/How%20To%20Enter%20an%20Allergy%20or%20Adverse%20Drug%20.ppt

*7. What is the difference between an **"Observed"** and **"Historical"** Adverse Drug Reaction?*

"Observed" means you or your colleague was made aware of an adverse outcome when the patient was, or was recently, on the drug. "Historical" refers to events in the distant past or that were observed in other healthcare settings. These terms are important because, typically, pharmacists review "Observed" reactions for possible reporting to the Food and Drug Administration (FDA).

The fact that a clinician does not physically "observe" and adverse drug reaction does not preclude reporting it as "Observed". For example, if a VA colleague provides an ACE Inhibitor to a patient, who then is seen at an outside facility for angioedema, it should be reported as "Observed" in CPRS.

8. Should any other information be provided?

Any additional information on the cause(s) of reaction may be relevant. Enter in enough information so that another reader may understand the severity of the reaction and the likelihood that the drug caused the reaction. For example, for a case of myositis caused by a fibric acid-HMG CoA Reductase combination, the following would be helpful, "Statin titrated to 40 mgs and then fibrate added, with subsequent muscle pain 1 month later. A suspected contributor was underlying renal insufficiency."

9. Is anything else done with the information?

Information that you provide on Observed reactions is reviewed by a pharmacist. Certain reactions must be reported to the FDA's MedWatch program including those that are associated with death, organ damage, disability, hospitalizations and emergency visits. In addition, any untoward reactions on newly-marketed drugs, typically within 3 years of release, need to be reported to the FDA. Reports are generally sent in by your facility's pharmacy service.

10. What if an individual provider wants to report a problem to the FDA?

Clinicians are encouraged to submit serious events to the FDA. MedWatch forms are on the FDA website http://www.fda.gov/medwatch/report/hcp.htm. Note that it t is important to report the information to your facility and/or enter the information into CPRS as well.

To learn more about FDA Adverse Drug Event Reporting Program, go to http://vapbm.org/Reporting%20Program.pdf.

11. What does the FDA do with MedWatch reports?

The information is used for post-marketing surveillance and for updating warnings and product labels. Hence, reporting is so important since only about 1% of serious and unexpected events are reported to the FDA.

12. Is a medication error similar to an adverse drug reaction?

No, not really, though they can lead to adverse drug reactions. Medication errors are **errors involving prescribing, dispensing, using or monitoring a drug**. Misreading a prescription is an example. It is estimated that up to 50% of medication errors are preventable. Medication errors that are stopped before harm can occur are sometimes called "near misses". Significant medication errors should be reported through the patient incident reporting system at a healthcare facility or may be done confidentially via the National Patient Safety Center at http://psrs.arc.nasa.gov/